

**Association of Golimumab Trough Levels
With Endoscopic and Histologic Healing in
Patients With Ulcerative Colitis
(GLMLEVEL)**

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Version 2

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PATIENT INFORMATION FOR CONSENT

Ulcerative colitis is a chronic disease characterized by chronic inflammation of the colon in which there are alternating periods of flares and remission of variable duration, when the patient does not present symptoms.

You are being treated with golimumab by decision of your doctor and you also have a colonoscopy planned, which result will help your doctor to assess the outcome of the treatment.

In ulcerative colitis, decisions are made fundamentally based on the clinical symptoms, however there are occasions in which laboratory results are very useful in case of doubt.

Golimumab levels in blood is one of these results, since depending on their presence / absence and quantity, your doctor will judge if the treatment is being effective and will take the appropriate measures.

Several studies have shown that high amounts of golimumab in blood are directly related to the clinical response. Also, low levels are related to a poor response to the drug. In studies carried out with similar drugs to golimumab, the presence in blood of adequate levels of drug was associated with the healing of the colon surface observed in a colonoscopy.

Likewise, golimumab levels are related to the state of the colon surface, which will be assessed in biopsies that are routinely taken during a colonoscopy.

Therefore, having a laboratory value that is obtained from a simple analytical to obtain information about the presence of drug in blood, would be very useful in daily clinical practice, resulting in an improvement in the quality of life for the patient.

1. Description of the study.

In the case you sign the informed consent, some data of your history will be stored in a database, which only the doctors who treat you will be able to consult.

When included in the study, on the day of the colonoscopy, a blood sample will be taken to analyze golimumab levels.

To perform a colonoscopy, you must perform a preparation with a diet low in waste and liquid diet in addition to taking 2 sachets of citrafleet the day before the test. All of this are in accordance with the usual clinical practice.

2. Benefits

You will not get any direct benefit or receive any financial compensation for participating in this study.

In the future, the information obtained in this study may facilitate the taking of therapeutic decisions and reduce the need for endoscopic examinations that are annoying and invasive and therefore improve their quality of life.

3. Risks

The study does not entail additional risks to those inherent in colonoscopy, since the measurement of golimumab levels is possible with a blood sample, in which the venous puncture required for sedation prior to colonoscopy will be used. The main risk of colonoscopy is the possibility of a colonic perforation, a fact that however occurs with a very low probability. Also, regarding colonoscopy, you should know that:

- In the hours prior to the realization of this test must have performed a cleanse of rectum and sigma, for it will be used one or two cleaning enemas applied a few hours before the procedure.
- The examination may be performed with or without sedation according to the guidelines of the endoscopy unit.
- In the case of sedation, a venous puncture will be performed; that can cause pain in the puncture site, hematoma or in exceptional cases a local inflammation (phlebitis) that is usually solved with local treatment and that is very infrequent that entails serious thromboembolic complications.
- The risk involved in taking biopsies is also very low, there is only scarce bleeding that usually heals without any intervention and only rarely is the cauterization of the wound necessary.

4. Voluntary participation.

Your participation in the investigation is totally voluntary and you will have the freedom to stop participating at any time, without needing to argue the reasons that lead you to this decision. The refusal to participate or the decision to withdraw from the study will not result in any sanction or harm in the future the medical attention you require.

5. Confidentiality.

All medical information resulting from your participation in this study will be stored and analyzed in an electronic database and will be treated confidentially

according to current legislation and following the laws of the Data Protection Agency. The results of the study may be published in scientific journals, but its name or clinical data that could identify it will not appear in any document.

The clinical data collected during the study will be used for research and will not be distributed to third parties, guaranteeing strict compliance with the General Data Protection Regulation (RGPD) 2016/679, of May 25th, 2018, with the same confidentiality treatment as the rest of your clinical history. Your identity will not be revealed in any report or article. You will be identified only by a number and your anonymous data will be included in an electronic file with restricted access. Access to your personal information will be restricted to the study doctor, health authorities (Spanish Agency for Medicines and Health Products), the Clinical Research Ethics Committee and personnel authorized by the sponsor, when they need to check the data and procedures of the study, but always maintaining the confidentiality of them according to current legislation. By signing the enclosed consent form, you agree to comply with the study procedures that have been presented to you.

With the signature of the attached informed consent, you expressly consent to the inclusion of the data of your clinical history as well as the results of your participation in the study in a Clinical Investigation File which is responsible for the Hospital and whose purpose is to carry out research studies. If you wish to access, revoke, cancel or oppose the inclusion of your data in the database, you may request it in writing to the Inflammatory Bowel Disease Unit, H Clinico San Carlos, C/Profesor Martín Lagos s/n. Email: ueii.hcsc@salud.madrid.org

6. Use of biological samples.

All samples, both blood and analytical, will be extracted and analyzed at the Hospital Clinico San Carlos. Part of the blood samples that are extracted will be analyzed immediately, while other will be stored temporarily for the determination of golimumab levels. Once determined, if there is a remainder of the sample, it will be destroyed. The biopsies will be processed according to the usual routine at the Hospital Clinico San Carlos. Once analyzed, they will be stored in the center indefinitely. Like your personal data, biological samples will be treated confidentially. You may request at any time to the study doctor the samples stored should be destroyed, or indicate any restriction in its use by addressing us at Inflammatory Bowel Disease Unit, H Clinico San Carlos, C/Profesor Martín Lagos s / n. Email: ueii.hcsc@salud.madrid.org.

7. Information.

The person in charge of the study (Dr.Taxonera) is a doctor of the Service of Gastroenterology in this hospital and he will give you all the complementary information you need regarding the study. You can contact him on the phone: 91 330 37 13.

INFORMED CONSENT

Study: **Association of Golimumab Trough Levels With Endoscopic and Histologic Healing in Patients With Ulcerative Colitis**

I, _____

(name and surname in capital letters)

I have read the information sheet that has been given to me.

I have received enough information about the study.

I have been able to ask questions about the study.

I have spoken with Dr.....

I understand that:

- My participation is voluntary.
- Participating in this study does not mean any benefit.
- The non-acceptance to participate in the study will not affect my medical attention.
- The information and results of this study are confidential.

Date:

Participant signature:

Date:

Researcher's signature: